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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,668	03/09/2001	Steven L. Roberds	PHRM-0319	3061

28523 7590 09/16/2005

PFIZER INC.  
PATENT DEPARTMENT, MS8260-1611  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/802,668

Applicant(s)

ROBERDS ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1649.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 95,96 and 117-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 95-96 and 117-123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Formal matters***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

### ***Response to Amendment***

2. Claims 95, 96 and 117-123 have been amended and claims 1-94 and 97-116 have been canceled as requested in the amendment filed on August 03, 2005. Claims 95-96 and 117-123 are pending in the instant application.

Claims 95, 96 and 117-123 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on August 03, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 101***

6. Claims 95, 96 and 117-123 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in previous office actions of record.

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At pages 4-5 of the Response, Applicant submits that utility analysis of *Brenner v. Manson* “is not analogous to the utility examination of the present antibody claims” and refers to the holding of *Noelle v. Lederman* stating that it “is directly and factually analogous to the pending antibody case”. Applicant further argues that utility of the instant polypeptide of SEQ ID NO: 105 is based on the disclosure of the identity of the polypeptide of SEQ D NO: 105 as an ion channel. Applicant’s arguments have been fully considered but are not persuasive for the following reasons.

The Examiner maintains the position that Applicant’s asserted utility of the polypeptide of SEQ ID NO: 105, particularly in view of lack of knowledge as to the biological significance of the polypeptide of SEQ ID NO: 105 or its association with a specific physiological or clinical condition, constitutes a utility that requires further research to identify or reasonably confirm a “real world” context of use. This type of utility is not considered a “substantial utility” pursuant to *Brenner* and USPTO Utility Examination Guidelines. If the polypeptide of SEQ ID NO: 105 does not have a substantial or well-established utility, it is unclear as to what is the specific and substantial credible utility of an antibody that binds to a polypeptide which lacks utility. To grant Applicant a patent encompassing an antibody to a naturally occurring human protein solely based on the assertion that the protein represents a novel human ion channel, would be to grant Applicant a monopoly “the metes and bounds” of which “are not capable of precise delineation”. That monopoly “may engross a vast, unknown, and perhaps unknowable area” and “confer power to block off whole areas of scientific development, without compensating benefit to the public” (*Brenner v. Manson, Ibid*).

Applicant's reliance on *Noelle v. Lederman* is misplaced. That court decision determined that the claimed antibody had sufficient support in written description, 35 USC § 112, first paragraph. Applicant is reminded that the instant rejection is a utility rejection, 35 USC § 101, and, therefore, the holding of *Noelle v. Lederman* is not applicable in the instant case. Furthermore, because the instant specification fails to disclose any specific and substantial credible utility for the claimed antibodies, holdings of *Raytheon* and *Juicy Whip, Inc.* appear to be also not relevant.

Therefore, for reasons fully explained in previous office communication, since the instant specification does not disclose a credible "real world" use for the claimed antibodies in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

***Claim Rejections - 35 USC § 112***

7. Claims 95, 96 and 117-123 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***New grounds of rejection necessitated by amendment***

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 95-96 and 117-123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 95, 96 and 117, as amended, appear to be duplicate claims because they are directed to the same subject matter despite some difference in wording. Applicant is advised to cancel the duplicate claims or to rewrite the claims to better express the claimed subject matter.

11. Claims 118-123 are indefinite for being dependent from indefinite claims.

### *Conclusion*

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870.

The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

September 14, 2005